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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,048	05/21/1999	LUC DESGROSEILLERS	10875.77	7290

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EXAMINER

SHUKLA, RAM R

ART UNIT PAPER NUMBER

1632

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/316,048

Applicant(s)

DESGROSEILLERS ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8 and 24-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-39 is/are allowed.
- 6) ☒ Claim(s) 4-8 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 28 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's response and amendment filed 5/5/04 and 6/7/04 is acknowledged.
2. It is noted that applicants in presenting there pending claim list indicated claims 1-3 and 9-18 as withdrawn. However, there claims were cancelled in the applicants amendment filed 6/19/02. Accordingly, these claims are not pending instantly.
3. New claims 30-39 have been added.
4. Accordingly, claims 4-8 and 24-39 drawn to human or mouse Staufen nucleic acid sequences are under consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4-8 and 24-29 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO 1, 3, 5, 6, and 7, (ii) an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO 8, SEQ ID NO 2, SEQ ID NO 4, amino acid residues 1-577 and 2-577 of SEQ ID NO 2, amino acid residues 2-487 of SEQ ID NO 8, and amino acids 2-496 of SEQ ID NO 4 and (iii) a nucleic acid complimentary to the full length nucleic acids of (i)-(ii), a recombinant vector comprising the isolated nucleic acid, a method of making a recombinant host cell comprising the isolated nucleic acid, a host comprising the nucleic acid, and a method of making the polypeptide encoded by the nucleic acid, does not reasonably

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provide enablement for a nucleic acid encoding proteins that have at least 95% identity to an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO 8, SEQ ID NO 10, SEQ ID NO 2, SEQ ID NO 4, amino acid residues 1-577 and 2-577 of SEQ ID NO 2, amino acid residues 2-487 of SEQ ID NO 8, and amino acids 2-496 of SEQ ID NO 4 wherein said nucleic acid have recited binding or hybridization property or other recited embodiments for reasons of record set forth in the previous office actions of 9-10-02 and 11/05/03. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

Applicant's arguments filed 5/5/04 have been fully considered but they are not persuasive.

Applicants have amended claims 4, 24 by including positive hybridization limitation or a negative hybridization limitation and binding activity to any RNA, HIV genomic RNA or tubulin. However, the limitation of binding to RNA, HIV genomic RNA or tubulin is not enabled because the specification does not teach conditions under which the recited nucleic acids could bind to the recited ligand. In fact the specification on page 55-56 while discussing the structure and function of Staufen discloses that staufen can bind to any dsRNA or RNA that form secondary structure or RNA/DNA hybrid which indicates that the binding is specific to any specific RNA substrate. Further, the specification on page 56 discloses:

15 the specificity are not known (Ferrandon et al., 1994). Since specific RNA binding cannot be obtained in vitro, it precludes the use of classic techniques to isolate and identify relevant RNAs which would bind staufen in vivo. Cross-linking of mRNA to staufen in vivo, and isolation of the resulting complexes will be necessary to identify the nature of bound RNAs.

In other words binding to RNA substrate may not be sufficient to isolate polynucleotides that encode a protein that bind to a specific RNA. Furthermore, it is

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noted that the claims are to a nucleic acid while the function is being studied of the protein encoded and thus an artisan would require extensive undue experimentation to isolate nucleic acids that would meet the recited functional characteristics since the specification does not teach which RNA would the Staufen protein encoded by the recited nucleic acids would specifically bind and under what conditions. Regarding the binding of the encoded protein to HIV genomic RNA, it is noted that the specification only shows that Staufen binds to TAR RNA and while the Staufen was present in the particles there is no evidence that binding to genomic RNA to Staufen could be reliably used for isolating the claimed nucleic acid molecules. It is emphasized that HIV genomic RNA is a large RNA molecule (more than 9 KB in size) and the specification does not teach how an artisan would make genomic HIV RNA and assay binding of a protein to the genomic RNA.

Therefore, the binding properties recited in the claims could not be used for isolating the nucleic acid molecules that would meet the claimed limitations.

Applicants' arguments have been fully considered however they do not address the issues raised above.

7. In view of the addition of the functional language, the written description rejection of claims 4 and 24 are withdrawn.

8. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The (i) embodiment of claim 4 recites a sequences hybridizes under recited conditions to a certain full length sequence (SEQ ID NO 1, 3, 5, 6 and 7) but does not hybridizes to parts of their sequences. The specification as filed does not describe any such nucleic acid sequences. Applicants indicated to pages 29 and 30 for support. However, these sections of the specification don't disclose any such nucleic acid molecules. Accordingly, this is considered a new matter.

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of invention recited in claim 4 is not clear because it is unclear with regards to embodiment (i) as to how a nucleic acid sequence could hybridize to the full length sequence but not to part of the sequence.

11. The invention of claims 30-39 is free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

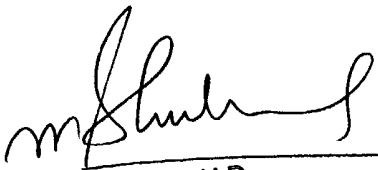
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is

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(571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632


**RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER**